JUN 1 8 2002

K021449

510(k) Summary of Safety and Effectiveness

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

Introduction

According to the requirements of 21 CFR 807.92, the following information provides sufficient detail to understand the basis for a determination of substantial equivalence.

Submitter name, Address, and Contact

Lin-Zhi International, Inc.
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Contact: Chiu Chin Chang, Ph.D.
VP, R&D

Device Name and Classification

(a) Classification Name:	Calibrators, Drug Specific; Class II, DLJ (91 Toxicology), 21 CFR 862.3200
Common/Usual Name:	Cannabinoid Calibrators
Proprietary Name:	None
(b) Classification Name:	Drug Specific Control Materials; Class I, LAS (91 Toxicology), 21 CFR 862.3280
Common/Usual Name:	Cannabinoid Controls
Proprietary Name:	None

Legally Marketed Predicate Device(s)

Lin-Zhi International, Inc.' Cannabinoid Urine Drugs of Abuse (DAU) Calibrators and Controls are substantially equivalent to the Δ^9-Cannabinoid (THC) Urine Calibrators and Controls (Diagnostic Reagents, Inc., now Microgenics Corporation), cleared under premarket notifications K923386 and 932113.

Device Description

All of the Cannabinoid Urine DAU Calibrators and Controls are human urine-based liquid, and ready to use. These Calibrators and Controls do not have any especially unique technical characteristics. They each contain a known concentration of 11-nor-Δ^9-THC-9-Carboxylic Acid.

All of the Cannabinoid Urine DAU Calibrators and Controls are prepared by spiking known concentrations of 11-nor-Δ^9-THC-9-Carboxylic Acid into the Negative DAU Calibrator, which is a processed, drug-free human urine-based matrix. The nominal concentrations of the analyte in the calibrators and controls are determined and confirmed by GC/MS.

Intended Use

The Cannabinoid Urine DAU Calibrators are intended for in vitro diagnostic use for the calibration of the Cannabinoid Enzyme Immunoassay to detect cannabinoids (THC) in human urine.

The Cannabinoid Urine DAU Controls are intended for in vitro diagnostic use for the validation of the Cannabinoid Enzyme Immunoassay to detect cannabinoids (THC) in human urine.

Comparison to Predicate Device

LZI's Cannabinoid Urine DAU Calibrators and Controls are similar in intended use, matrix, and performance to the DRI's Δ^9-Cannabinoid (THC) Urine Calibrators and Controls.

Similarities:

Both are for the calibration and validation of Cannabinoid Enzyme Immunoassay to detect cannabinoids (THC) in human urine.

- The cutoff concentration(s) for the analyte are the same, which include the cutoff of 50 ng/mL per recommendation of The Substance Abuse and Mental Health Services Administration (SAMHSA) for the initial screening test of cannabinoids (THC) abuse. The nominal concentrations of the analyte in the calibrators and controls are determined and confirmed by GC/MS.
- Both are urine-based liquids.
  Storage condition is the same, at 2°C to 8°C.
  Performance characteristics on precision, accuracy and stability are similar.

Comparison to Predicate Device (continued)

Differences:

Characteristics	DRI's Δ^9-Cannabinoid (THC) Urine Calibrators and Controls	LZI's Cannabinoid Urine DAU Calibrators and Controls
No. of Calibrators	5 levels including the Negative Calibrator.	A total of 9 levels including the Negative Calibrator are available.
No. of Controls	4 levels of controls available	2 levels of controls for each cutoff assay.
Concentration of Analyte	0, 20, 40, 50, 60, 75, 100, 125, and 200 ng/mL	0, 10, 20, 30, 37.5, 50, 62.5, 75, 100, 125, 150, and 200 ng/mL

Conclusion

The information provided in the premarket notification demonstrates that the LZI's Cannabinoid Urine Drugs of Abuse Calibrators and Controls are substantially equivalent to previously approved predicate devices, notably the DRI's Δ^9-Cannabinoid (THC) Urine Calibrators and Controls, and safe and effective for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

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Chiu Chin Chang, Ph.D.
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2391 Zanker Road, Suite 340
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Re: k021449
Trade/Device Name: Cannabinoid Urine Drugs of Abuse Calibrators and Controls
Regulation Number: 21 CFR 862.3200
Regulation Name: Clinical Toxicology Calibrator
Regulatory Class: Class II
Product Code: DLJ
Dated: April 29, 2002
Received: May 6, 2002

Dear Dr. Chang:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Premarket Notification

Indications for Use Statement

510(k) Number (if known): K021449

Device Name: **Cannabinoid Urine Drugs of Abuse Calibrators and Controls**

Indications for Use:

The Cannabinoid Urine Drugs of Abuse (DAU) Calibrators are intended for in vitro diagnostic use for the calibration of the Cannabinoid Enzyme Immunoassay to detect cannabinoids (THC) in human urine.

The Cannabinoid Urine Drugs of Abuse (DAU) Controls are intended for in vitro diagnostic use for the validation of the Cannabinoid Enzyme Immunoassay to detect cannabinoids (THC) in human urine.

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K021449

Concurrence of CDRH, Office of Device Evaluation (ODE)

✓
Prescription Use **OR** **Over-The-Counter Use**
(Per 21 CFR 801.109)

(Optional Format 1-2-96)